dimensional model of the instrument with group type (exercise or control) as the criterion variable to assess model invariance. **RESULTS:** A total of 89 participants completed the trial of which 48 were in the exercise group. Evidence of variation in the factorial structure of the EPDS between groups was found suggesting the invariance assumption may not be supported. **CONCLUSIONS:** The assumption that the outcome measure (EPDS) is invariant between groups within an RCT was not supported. Further investigation is required to evaluate the impact of outcome measure variance on treatment effects in clinical trials where self-report measure data is used as primary and/or secondary outcomes.

INDIVIDUAL'S HEALTH – Cost Studies

PIH9

TRENDS IN IUD INSERTIONS AND RELATED MEDICAL EXPENDITURE IN THE UNITED STATES: THE POPULATION WITH EMPLOYER-SPONSORED INSURANCE

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OBJECTIVES: The prevalence of intrauterine device (IUD) use is low among women of reproductive age in the United States. The objective of this study was to examine the trend in IUD insertions and related medical expenditures between 2002 and 2007 in a population of women covered by employer-sponsored health insurance (ESI). **METHODS:** We conducted a population-based study using the MarketScan Commercial Claims and Encounter Enrolled Population database. We identified women, 15–49 years old who filed a claim for the insertion of an IUD or IUS (the Levonorgestrel-releasing IUD) between January 1, 2002 and December 31, 2007. We adopted the MarketScan national weights in order to generate nationally representative estimates. **RESULTS:** The number of new IUD/IUS patients in the ESI-covered population doubled, from 70,851 (2/1,000 eligible women) in 2002 to 154,366 (8/1,000) in 2007. Meanwhile, the market share of the IUS increased from 35% to 80% of all IUD insertions. The mean copayment for IUD (IUS) devices decreased from $13.0 ($14.6) in 2002 to $3.5 ($3.6) in 2007 after adjusting for inflation (in 2007 dollars), and the percent of patients with zero copayment for the device and for the insertion procedure increased from 65% to more than 80% and form 58% to 73%, respectively. The average net reimbursement for the IUD increased 17.5% between 2002 and 2007, from $311.92 to $366.64, while that for the IUS increased 7.5%, from $405.36 to $435.49. **CONCLUSIONS:** The increase in medical expenditures associated with IUD/IUS insertions from 2002 to 2007 was driven by the growth in IUS insertions. IUDs have lower contraceptive failure rates than other reversible contraceptive methods, and higher rates of IUD use should lead to fewer unwanted pregnancies. Additional research is needed to understand whether the recent growth in IUS insertions is related to changing provider attitudes and more favorable insurance coverage.

PIH10

TREATMENT PATTERNS AND ECONOMIC BURDEN OF UTERINE FIBROIDS IN A UNITED STATES MANAGED CARE DATABASE

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OBJECTIVES: To document surgical treatment patterns of uterine fibroid (UF) patients and total all-cause medical costs for UF patients in real-world practice settings using managed care claims data. **METHODS:** In this retrospective database study, women with a UF diagnosis between 15 and 51 years of age were selected between 2000 and 2006. An index date was defined as the date of first observed UF diagnosis. All patients were required to have continuous plan enrollment 6 months pre- and 36 months post-index date. Summary statistics for patient characteristics, probability of first UF-related surgery, any repeat UF-related surgery, and total medical and pharmacy costs (2007 US$) incurred 12 months post-index date were generated. **RESULTS:** A total of 109,595 patients met the study inclusion criteria. The mean age at UF diagnosis was 43 years and the mean Charlson score was 0.27. Patients with commercial insurance accounted for 91% of the population, while 75% had an HMO or PPO plan. The probability of UF-related surgery was 30.2%, 35.0%, and 38.4% within the 12-month, 24-month, and 36-month follow-up periods, respectively. Among patients with a UF-related surgery during the 36 month follow-up period, 79.6%, 7.3%, 3.3%, 13.0% had hysterectomy, myomectomy, UAE/UAO, and ablation, respectively. Mean age at first surgery (44 years) varied by surgery type with younger women more likely to undergo myomectomy. The rate of repeat surgery within one year of first surgery ranged from 1.6% (hysterectomy) to 10.5% (ablation). The mean total cost for all UF patients was $9608, 12 months post-index date. **CONCLUSIONS:** A substantial proportion of patients undergo UF-related surgeries within one to three years of diagnosis, with hysterectomy being the most common surgery. UF-related surgeries present significant clinical and economic implications that should be understood by private and public third party payers who bear the financial burden of UF surgical care.

PIH11

THE BURDEN OF ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD) ON PATIENTS HOSPITALIZED WITH A PRIMARY DIAGNOSIS OF OPPOSITIONAL DEFIANT DISORDER (ODD)

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OBJECTIVES: To assess length of stay (LOS) and costs attributable to ADHD among adolescents hospitalized with a primary diagnosis of ODD. **METHODS:** Patients 12–17 years old with a primary diagnosis of ODD (ICD-9-CM code 313.81) were selected from the 2000 to 2006 Health care Cost and Utilization Project Nationwide Inpatient Sample (HCUP-NIS). Patients with a diagnosis of ADHD (ICD-9-CM codes 314.00 and 314.01) comprised the study cohort and patients without an ADHD diagnosis comprised the control cohort. Study measures included demographics, hospital characteristics, admission source, discharge disposition, LOS, and costs. Generalized linear models accounting for the HCUP-NIS survey design were undertaken to adjust LOS and cost estimates. **RESULTS:** A total of 7,404 and 18,039 patients met the inclusion criteria for the study and control cohorts, respectively. Patients in the study cohort were 6.8 months younger than patients in the control cohort (13.8 versus 14.4 years). A higher percentage of patients in the study cohort were male (71.3% versus 45.2%) or had Medicaid (57.1% versus 48.6%) compared to the control cohort. In both cohorts, the ER was the most common admission source, approximately 90% of patients had their discharge disposition recorded as routine, and most patients were treated in urban, teaching, or large bedsize hospitals. The study cohort had longer LOS and higher costs versus the control cohort (mean [SE] 9.48 [0.89] days and $8241 [$1356] versus 7.90 [0.59] days and $6466 [$709]). Regression analyses found the study cohort had significantly longer LOS and higher costs versus the control cohort (by 2.5 days and $1338). **CONCLUSIONS:** Patients hospitalized with a primary diagnosis of ODD and a secondary diagnosis of ADHD had significantly longer LOS and higher costs compared to patients with ODD but without ADHD. Clinicians and health care decision-makers should be aware of the impact ADHD has on inpatient stays among patients with ODD.

PIH12

DULOXETINE DOSING PATTERNS AND HEALTH CARE COSTS AMONG ELDERLY DIAGNOSED WITH FIBROMYALGIA

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OBJECTIVES: This study employed a retrospective cohort design to examine patterns of duloxetine utilization and health care costs among elderly fibromyalgia patients. **METHODS:** Pharmacy and medical claims were analyzed for fibromyalgia patients aged 65+ with Medicare supplemental insurance who initiated duloxetine in 2006. The index date was defined as the dispense date of the first duloxetine prescription filled, with no duloxetine coverage in the prior 90 days. Patients were required to have at least 30 supply days of duloxetine in the 12 months post-index period. Individuals with any diagnosis of diabetic peripheral neuropathic pain or depression during the 12 months pre-index period were excluded. Five study cohorts were constructed based on the index dosage: <30 mg, 30 mg, 31–59 mg, 60 mg, and >60 mg. Patterns of duloxetine use including changes in dosage, average daily dose (ADD), adherence to duloxetine (medication possession ratio≥0.8 as high adherence) were examined across study cohorts. Regression models were performed to estimate the differences in health care costs. **RESULTS:** A total of 566 fibromyalgia patients were included, with 41, 163, 47, 294 and 21 in the <30 mg, 30 mg, 31–59 mg, 60 mg, and >60 mg cohorts, respectively. A total of 31.4% of patients experienced any dosage changes (increased dosage: 25.8%; decreased dosage: 15.7%). Among those who changed dosage, patients in the 31–59 mg cohort had the shortest time to change (81 days), and patients in the <30 mg cohort had the longest (149 days) time. ADD trended upward as index dose increased. Compared with patients in the 60 mg cohort, those in the <30 mg and >60 mg cohorts were less likely to be adherent (odds ratios 0.40 and 0.30, respectively, both $p < 0.05$). Post-index total health care costs were similar across cohorts. **CONCLUSIONS:** Dosage changes occurred most quickly in fibromyalgia patients with an index dose of 31–59 mg of duloxetine. Duloxetine ADD and adherence differ by index dosage, while health care costs remain similar.

PIH13

HEALTH CARE UTILIZATION AND COSTS FOR THE TREATMENT OF HYPOACTIVE SEXUAL DESIRE DISORDER

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OBJECTIVES: Hypoactive sexual desire disorder (HSDD) is characterized by persistent/ recurring deficiency of sexual fantasies or thoughts, and/or the absence of desire for sexual activity. Despite the potentially high prevalence of the condition, few studies have evaluated the cost of treating women with HSDD. The current study describes health care utilization and costs among women suffering from HSDD relative to women without evidence of female sexual dysfunction (FSD). **METHODS:** Women aged 18–64 with a diagnosis of HSDD (ICD-9-CM: 302.71) were identified using the Marketscan® Commercial Claims and Encounters Databases from Thomson Reuters. Women were identified between January 1, 1998-December 31, 2007 and were matched 1:3 to women without FSD (ICD-9-CM: 302.7x; 306.51) based on age, health plan type and months with medical/pharmacy benefits. Utilization and costs were evaluated during the 12, 24 and 36- month periods following HSDD diagnosis.

RESULTS: A total fo 3,975 women with HSDD and 11,925 controls were identified for the 12-month follow-up period. Women with HSDD had significantly fewer inpatient admissions (0.07 vs. 0.09) and more general outpatient medical (29.26 vs. 19.13), behavioral health office (1.82 vs. 0.71) and more radiology (3.10 vs. 2.30) visits in the 12-month follow-up period versus controls. Cost differences were also observed among women with HSDD relative to their controls—with greater costs for general outpatient medical ($3427), behavioral health office ($197) and radiology ($515) visits in the 12-month follow-up period among women with HSDD than for controls (general outpatient medical visits: $2334; behavioral health office visits: $77; radiology visits: $377; all $p < 0.001$). Differences in utilization and costs persisted in the 24 and 36-month follow-up periods. **CONCLUSIONS:** Women with HSDD have higher 'downstream' costs than women without any sexual dysfunction. The development of treatment modalities that effectively control HSDD symptoms may present an opportunity to better manage health care utilization and costs in this population.

PIH14

COST-EFFECTIVENESS OF A HIGHLY PURIFIED HUMAN MENOPAUSAL GONADOTROPIN (HP-HMG) VERSUS RECOMBINANT FOLLICLE-STIMULATING HORMONE (RFSH) IN PATIENTS PARTICIPATING IN AN ASSISTED REPRODUCTIVE TECHNOLOGIES (ART) PROGRAM

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OBJECTIVES: To determine the cost-effectiveness of HP-HMG (menotropin, MENOPUR®) compared to rFSH (follitropin alpha, GONAL-F®), in producing live births in the ovulatory patient participating in an ART Program. **METHODS:** A previously validated and published European Markov model was adapted to the Canadian setting to estimate the incremental cost per additional live birth gained for HP-HMG compared to rFSH, projected over three treatment cycles. These cycles included an initial fresh cycle then two additional cycles, as needed, of either fresh or cryoperserved embryos. Live birth rates were derived from a published meta-analysis comparing HP-HMG menotropin to rFSH follitropin alpha. Factors such as discontinuation, ooctye fertilization and pregnancy rates were derived from the published literature. All clinical outcomes were validated against published Canadian ART registry data and through clinical expert review. The analysis focused on direct medical costs only from the perspective of a provincial public health care system (Quebec). Cost data were obtained from a variety of sources including published references, provincial health care sources and expert opinion. All costs were reported as 2009 Canadian Dollars ($CAD). Given the short time-horizon discounting was not applied. Multiple sensitivity analyses were undertaken to test the robustness of the model to variations in key parameters including the cost and relative outcomes of comparators. **RESULTS:** The base case analysis indicates that HP-HMG results in a total cost per patient of $CAD 11,742 over 3 cycles compared to $CAD 13,202 for rFSH. Further, treatment with HP-HMG results in more live births than rFSH with 0.485 versus 0.421, respectively. Thus, treatment with HP-HMG is dominant relative to rFSH (less costly and more effective). Results were robust over multiple sensitivity analyses. **CONCLUSIONS:** Treatment with HP-HMG (MENOPUR) is cost-effective compared to rFSH (GONAL-F), providing a greater number of live births at a lower cost to the public health care system.

PIH15

COST EFFECTIVENESS ANALYSIS OF FDA APPROVED ORAL EMERGENCY CONTRACEPTIVES

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OBJECTIVES: Unintended pregnancies, a health problem with significant economic burden on US could be avoided by use of FDA approved oral emergency contraceptives (ECPs) namely Plan B one-step (one pill regimen) and Next choice (two pill regimen). The objective of this study was to conduct a head-to-head comparison of these oral ECPs. **METHODS:** A cost effectiveness (CE) decision tree model was developed using data from published randomized controlled trails (effectiveness values) and primary data collection. Cost of each drug was obtained by taking an average of the price of drug from 5 large chain pharmacies. Outcomes considered were no pregnancy, birth, induced abortion, spontaneous abortion or ectopic pregnancy. Cost and probabilities of each outcome was derived from past literature and included only the direct costs. All adverse events with a probability of more than 5% and the direct cost associated with treating each of those adverse events were considered. These adverse events generally last for duration of one week, which was used to derive cost information for adverse events. The analysis involved only a onetime cost of taking an emergency contraceptive. Results were validated using one way and two way sensitivity analyses by varying the cost and effectiveness by a range of 25% each. **RESULTS:** The brand name drug Plan B one-step as opposed to the generic counterpart available, Next Choice, emerged as the cost effective option to avoid unintended pregnancy. The cost of treatment with Plan B one-step was $859 as opposed to $1075 for Next Choice. Two-way sensitivity analyses were robust and indicated that treatment with Plan B one-step completely dominated Next Choice. **CONCLUSIONS:** Plan B one-step; a one pill emergency contraceptive drug, with a higher retail price was found to be more cost effective than Next Choice.

PIH16

COST-EFFECTIVENESS ANALYSIS FOR TREATMENT OF SYMPTOMATIC UTERINE FIBROIDS AMONG PREMENOPAUSAL WOMEN SEEKING TO RETAIN UTERUS

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OBJECTIVES: To determine the cost-effectiveness of different treatment options and optimal number of treatments for symptomatic uterine fibroids among premenopausal women who would prefer to retain uterus. **METHODS:** A Markov model with a 1-year cycle length was developed. Women entered the model at diagnosis with symptomatic fibroids and were followed to menopause or age 60 years, when all women were assumed to reach menopause. Treatment options included watchful waiting, myomectomy, and one-time, 6-month use of gonadotropin-releasing hormone (GnRH). In the model, women treated unsuccessfully or whose symptoms recurred could undergo up to three additional treatments or stop treatment at any point. Data on treatment efficacy, quality-of-life, and medical costs (2007 US$) were from published studies. For myomectomy, the probabilities of repeat procedures and of emergency hysterectomy were from a large US claims database analysis. Age-specific rates for pregnancy and menopause were based on US data. Total costs and quality-adjusted life years (QALYs), discounted annually at 3%, were calculated for each treatment strategy for women diagnosed at different ages. Incremental cost-effectiveness ratios (ICERs) were calculated and an efficiency frontier was plotted. **RESULTS:** Base-case results for women diagnosed at age 20 years showed treatment strategies including GnRH were dominant compared with treatment strategies including myomectomy only and were cost-effective compared with watchful waiting (ICER range: $3789-$7456 per QALY gained). Additional procedures for women whose symptoms recurred led to increased medical costs and QALYs, resulting in an incremental cost per QALY gained of $13,307, $15,433, and $17,555 for the second, third, and fourth myomectomy, respectively. Results were sensitive to age at diagnosis, number of treatments, and the disutility associated with a woman losing her uterus via emergency hysterectomy. **CONCLUSIONS:** This model is the first to assess the cost-effectiveness and optimal number of treatments specifically for a woman with fibroids seeking to retain her uterus.

PIH17

COST-EFFECTIVENESS ANALYSIS OF FOUR EMBRYO TRANSFER STRATEGIES

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OBJECTIVES: The objective of this study was to evaluate the cost and clinical outcomes of single versus double embryo transfer using cleavage-stage or blastocyst-stage embryo in assisted reproduction. **METHODS:** Markov model was designed to simulate outcomes of: 1) single-(cleavage-stage) embryo transfer (SET); 2) double-embryo transfer (DET); 3) single-blastocyst transfer (SBT); and 4) double-blastocyst transfer (DBT). Model inputs were estimated from literature and cost analysis was conducted from health care provider's perspective. **RESULTS:** The base-case analysis showed that DBT was the most costly (US$5173) and effective strategy (birth rate = 0.311) in fresh cycle. The cumulative cost and birth rate of SET were the highest in all cycles. Monte Carlo 10,000 simulations showed that the probability of DBT to be cost-effective in fresh cycle was the highest when willingness-to-pay (WTP) per live birth was ≥US$85,000. In all cycles, the probability of SET to be cost-effective was the highest when WTP was ≥US$50,000. **CONCLUSIONS:** CONCLUSIONS DBT appears to be the most costly and most effective strategy in fresh cycle whereas SET seems to have the highest cumulative cost and live birth rate.

PIH18

ANALYSIS OF NECROTIZING ENTEROCOLITIS COSTS AMONG EXTREMELY PRETERM INFANTS FED EXCLUSIVELY HUMAN-MILK BASED DIET VS. HUMAN-MILK FORTIFIED WITH BOVINE-MILK BASED SUPPLEMENTS

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OBJECTIVES: To estimate the incremental costs of necrotizing enterocolitis (NEC) among extremely preterm infants (GA < 28 weeks) and to evaluate the cost-effectiveness of an exclusively human-milk based diet (fortified with Prolacta + HMF™) vis-à-vis human-milk fortified with a bovine-milk based supplement in the prevention of NEC. **METHODS:** California OSHPD 2007 hospital discharges database was used to estimate the incremental costs of NEC and surgical NEC among all preterm infants. Costs were adjusted for confounding by demographics, gestation age, mortality and comorbidities. Expected medical costs of NEC among extremely preterm infants fed either exclusively human-milk based diet or human-milk fortified with bovine-milk based fortifier were calculated based on findings from a randomized controlled trial comparing neonatal outcomes of extremely preterm infants fed either of these diets. **RESULTS:** The adjusted incremental costs of NEC and surgical NEC among extremely preterm infants in 2009 US$ were 69,185 and $198,490 respectively per infant ($p < 0.0001$). Expected medical costs of NEC were higher among infants fed human-milk fortified with bovine-milk based supplement resulting in net savings of $16,875 per infant for infants fed exclusively human-milk based diet ($p < 0.0001$). The societal costs savings for the US population of premature infants is estimated to be US$